

Instructions for the NCS Hypothesis Rating System

In this section you will find the criteria needed to rate the 29 hypotheses proposed by The Lewin Group for inclusion in the National Children's Study. These criteria have been grouped into three categories: (1) Public Health Significance, (2) NCS Study Design Considerations, and (3) State of Research on the Topic. Definitions for each criterion are provided for your reference. In addition, a description of the National Children's Study has been provided that explains the scope and initial design of the study. This description can be found at the front of this binder.

For each proposed hypothesis, please complete a rating form using the aforementioned criteria. Specific instructions for using the criteria to rate the hypotheses can be found on the rating form. For each form, please make sure you place your name on the form as well as the hypothesis number for which the form was completed. We also ask that you provide your comments or suggestions regarding the hypothesis on the back of the form. Thirty copies of the rating form have been provided for your convenience; please make additional copies of the form, if needed.

In addition to providing feedback on the proposed hypotheses, we encourage you to suggest any additional areas of focus and/or specific hypotheses regarding environmental influences on children's health that you feel are important for investigation in the National Children's Study. Please use the rating system provided to rate any additional areas of focus and specific hypotheses you propose and provide some rationale on why they should be considered for inclusion in the National Children's Study.

Once you have completed the rating forms, please mail or fax copies of the forms (keep the originals for your reference) to The Lewin Group *prior to our scheduled call with you*. Please mail copies of the forms to the following address:

The Lewin Group
3130 Fairview Park Drive, Suite 800
Falls Church, VA 22042

If you choose to fax the copies of the forms, please be sure to photocopy and fax any comments/suggestions provided on the back of the rating forms. Copies of the forms can be faxed to the attention of The Lewin Group at fax# 703-269-5501.

Please do not hesitate to contact The Lewin Group at (703) 269-5500 if you have any questions regarding the rating system.

Criteria for the NCS Hypothesis Rating System

	Public Health Significance						
Criterion	Prevalence	Incidence	Mortality Rate	Clinical Burden (Disease Severity/Disease Burden)	Economic Burden (Costs to Individual or Family/ Costs to Society)	Frequency/Load of Exposure	Special Populations
Definition	The number of existing cases in a given population at a single point in time or over a period time.	The number of new cases in a given population over a period of time.	The ratio of the number of deaths from a disease in a population to the total population over a period of time.	How severe/debilitating the disease is to the individual. (and family, as appropriate), and to the population or society at large.	How costly the disease is to the individual (or family) and to the population or society at large.	How frequent or extensive the exposure to the environmental toxicant is in the population.	Exposures or disease outcomes that may appear more often in special populations than in the general population.
Items to Consider	Trend of prevalence (increasing, decreasing, remaining the same)	Trend of incidence (increasing, decreasing, remaining the same)	Trend of mortality (increasing, decreasing, remaining the same)	Case fatality (Ratio of deaths in a given year to total incident cases in that year) Chronic or acute condition Type and frequency of medical treatment (i.e., hospitalizations) Effect of disease on quality-adjusted life years (QALYs)	Cost of treatment Cost of lost productivity (e.g., by patients and family/ caretakers)		Frequency of exposure/ prevalence of disease outcome in a particular race, sex, or age group Frequency of exposure/ prevalence of disease outcome in a particular region or community (e.g., inner cities, farms) Frequency of exposure/ prevalence of disease outcome in a families with a particular type of laborer (e.g., migrant farm workers, chemical plant workers)

Criteria for the NCS Hypothesis Rating System (continued)

	NCS Study Design Considerations					Status of Current Research	
Criterion	Timing of Exposure and Outcome	Ascertaining Exposure and Outcome	Sample Size	Potential for Follow-up/Tracking	Generalizability	Nature of Current Research	Research Needs
Definition	The time at which the exposure occurs	Detection and measurability of the exposure	The number of people required to detect an association between the exposure and disease or condition	Ability to follow-up/track individuals in the study	Ability to apply study findings to the population at risk	Status of the current research on the exposure and related disease outcome	The need for further research on the exposure and disease outcome.
Items to Consider	Prenatal/perinatal/post-natal/early childhood/late childhood Appropriateness for NCS study design	Frequency of exposure Measurability of the exposure (quantitative)	Appropriateness for NCS study design	Potential ease for follow-up of individuals with disease outcome Appropriateness for NCS study design	Generalizability of past and current research to the total population at risk	The quality of research that exists on the association between the exposure and outcome (esp. internal validity) How long exposure and outcome have been studied Funding spent on past and current research Extent to which research exists on association between exposure and outcome in groups representative of total population at risk (external validity/generalizability)	Call for more research Unanswered research questions regarding the association between the exposure and outcome